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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/533,611 | 05/11/2006 | Hyoung-Joon Jin | TUV-031.01 | 6317 |

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| EXAMINER | |
|---|---|
| DESAI, ANAND U | |
| **ART UNIT** | **PAPER NUMBER** |
| 1656 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 12/11/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/533,611 | JIN ET AL. | |
| | Examiner | Art Unit | |
| | ANAND U. DESAI | 1656 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *1-15 and 24-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16 and 18-23* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

3. This office action is in response to the amendment filed on July 22, 2008. Claims 1-15 and 24-48 have been withdrawn previously.

4. Claims 16-23 are currently pending and are under examination.

### Pending Rejections

#### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 16 and 18-23 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of obtaining predominantly one enantiomer from a mixture of enantiomers, comprising the steps of: a. contacting an aqueous fibrous protein solution, wherein the fibrous protein is selected form a group consisting of silk, collagens, keratins, actins, chorions, and seroins with a solvent that is not miscible with water, wherein the solvent is selected form a group consisting of hexane, chloroform and iso-amyl alcohol; b. allowing the solution in contact with the solvent to age at about room temperature or under conditions preventing evaporation or both; c. allowing the enantiomers of the mixture to diffuse selectively into the resulting fibrous protein smectic hydrogel in solution; d. removing the smectic hydrogel from the

solution; e. rinsing predominantly a first enantiomer from the surface of the smectic hydrogel; and f. extracting predominantly a second enantiomer from the interior of the smectic hydrogel, does not reasonably provide enablement for a method of obtaining predominantly one enantiomer from a mixture of enantiomers, comprising the steps of: a. contacting an aqueous fibrous protein solution wherein the fibrous protein is any fibrous protein with a solvent that is not miscible with water, wherein the solvent is any solvent that is not immiscible with water; b. allowing the solution in contact with the solvent to age at about room temperature or under conditions preventing evaporation or both; c. allowing the enantiomers of the mixture to diffuse selectively into the resulting fibrous protein smectic hydrogel in solution; d. removing the smectic hydrogel from the solution; e. rinsing predominantly a first enantiomer from the surface of the smectic hydrogel; and f. extracting predominantly a second enantiomer from the interior of the smectic hydrogel. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Response to Remarks

7. Applicant's state that the amount of experimentation necessary to enable the claimed methods of obtaining predominantly one enantiomer from a mixture of enantiomers is not undue for one reasonably skilled in the art when interpreted in light of the guidance provided in the specification. Applicant's cite the examples of solvents that are not miscible with water that have varying molecular structures, molecular weights, hydrogen-bonding capabilities and polarities and states that one of skill in the art could readily conceive of a myriad of suitable alternatives with similar structural diversity, with

some routine screening that could produce the results. Applicant's state the fibrous proteins provide sufficient guidance and the sequences need not be restricted to the specific classes cited by the examiner in order for the claimed method to be enabled. Applicant's state with knowledge of the general structure of fibrous proteins, and the direction provided by the specification, a person of ordinary skill in the art could engineer peptides with specific sequence patterns that, with only routine experimentation, could form the smectic hydrogels used in the claimed methods.

Applicant's arguments filed July 22, 2008 have been fully considered but they are not persuasive. The specification states the choice of solvent, starting concentration of protein, and environmental factors such as temperature, humidity, addition of ether and/or alcohol to the protein solution, addition of acid, and addition of divalent ionic salts will result in different permeation properties for the protein materials. In addition, the specification states that highly structured templated solid materials (i.e smectic hydrogels) cannot be obtained for silks below concentrations of about 4 wt% protein (see page 17, lines 17-20). There is undue experimentation for the use of any aqueous fibrous protein solution to make a smetic hydrogel as currently claimed. The issue in this application is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan, and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher, 427 F. 2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)* where it is stated that "… scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art…". Without sufficient guidance, determination of having the

desired biological characteristics is unpredictable and the experimentation left to those skill in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, *858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)*. Therefore, absent direction/guidance regarding whether the repeat protein polymer identified by formula can tolerate the modifications contemplated a non-functional repeat protein polymer may result and one of skill in the art would not be able to practice the claimed invention commensurate in scope with the claims.

### *Claim Objections*

8. Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Conclusion*

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

December 8, 2008
/ANAND U DESAI/
Primary Examiner, Art Unit 1656